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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/446,677	03/24/2000	SVEND BIRKELUND	BIRKELUND=1	2720

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/446,677	BIRKELUND ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,15-18,22-25 and 27-33* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5, 7, 10, 22-25 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 1-4, 6, 8, 9, 11, 13 and 15-18 and Species SEQ ID NO:4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24 .

RESPONSE TO AMENDMENT

The amendment filed 9-12-05 has been entered into the record. Claims 1-11, 13, 15-18, 22-25 and 27-33 are pending. Claims 12, 14, 19-21, 26 and 34-44 have been cancelled. Claims 5, 7, 10, 22-25 and 27-33 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Any objection or rejection not maintained herein is withdrawn.

Election/Restrictions

This application contains claims 1-4, 6, 8, 11, 13 and 15-18 and Species SEQ ID NO:4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24 are drawn to inventions nonelected with traverse in the responsive paper of 2-27-02 and 3-5-02.

Applicants have previously argued the lack of unity that the generic claim was allowable. This is not persuasive, the elected claim 5, SEQ ID NO:2 does not share the same technical feature among the alternatively recited Markush members of SEQ ID NOS: 4, 6, 8, 10, 12, 16, 18, 20, 22 or 24. Each of the claimed Markush members are polypeptides that have a different primary sequence structure and as such are not liked by a special technical feature within the meaning of PCT 13.1. Claim 5 is not a generic claim, but a Markush claim now providing for structurally different members not linked by the same special technical feature. The recitation of "derived from *Chlamydia pneumoniae*" does not provide for the same special technical feature of the claimed polypeptides. As such, the claim is not generic to each alternatively claimed member and each member as now claimed recites a different special technical feature.

Objections/Rejections Withdrawn

The objection to the specification as lacking sequence identifiers is withdrawn in view of Applicants' amendments to the specification.

The rejection of claims 5, 7, 10, 22-25 and 27-32 under 35 USC 112, first paragraph as failing to comply with the written description requirement as new matter for the term "a non-naturally occurring" is withdrawn based on Applicants' amendment.

The rejection of claims 31 and 32 under 35 USC 112, second paragraph is withdrawn in view of the amendment to the claims.

Rejections Maintained

The rejection of claims 5, 7, 10, 22-25 and 27-32 under 35 USC 112, first paragraph as failing to comply with the written description requirement is maintained for reasons made of record in the Office Action mailed 3-11-05 and herein.

Applicants' arguments have been carefully considered but are not persuasive. The claim state ""consists of an amino acid sequence which is a subsequence, at least 6 amino acids in length, of at least one of said isolated proteins of (i) above, said subsequence comprising at least one T cell epitope of at least one of said isolated proteins of (i) above." The claims are drawn to T cell epitope subsequences from a single protein of (i) and combinations of T cell epitopes from subsequences of the proteins of (i) [i.e. as it relates to the recitation of "at least one of"]. The written description of the specification must provide conception of the new subgenera of fragments claimed. The specification provides for at least 6 amino acids in length at page 15, last paragraph. This paragraph does not provide for conception of T cell epitopes, nor does it provide for a protein or peptide having a combination of T cell epitopes or 6 amino acid fragments of the recited protein in claim 5 (i). Applicants point to page 17 that recites: "It is envisioned that particularly interesting and immunogenic epitopes will be found in connection with the proteins of the invention, which will comprise subsequence of said proteins." Applicants argue that each of the proteins necessarily comprise a T cell epitope. This is not persuasive, the claims are not drawn to the entire protein. Applicants argue that the skilled artisan would use testing to identify T cell epitopes or search for such by using methods in the art. This is

not persuasive, the standard for written description is not to make and test to discover such, but possession, conveyed by an adequate written description in the specification as filed. Applicants' passage at page 17, lines 30-18 are merely prophetic. This passage is broader than T cell epitopes. The specification does not provide for description of a single peptide subsequence that provides for a T cell epitope. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. Applicants' have no written description for any of these T cell epitopes and that applicants' are not entitled for dominance of further patentable inventions by claims that are insufficiently supported by the specification (*In re Fisher*, 166 USPQ 18, CCPA (1970)). It is noted that entitlement to a filing date does not extend to subject matter that is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). Further, the property of "immunogenic" is defined in the art as "capable of inducing humoral immunity or cell-mediated immunity but not immunological tolerance" (Herbert et al, The Dictionary of Immunology, Academic Press, Fourth Edition, 1995, page 90). The specification fails to describe a subsequence with these properties and relies upon a paragraph of the specification that is prophetic. Further, this paragraph does not provide for combining different epitopes from different proteins of (i), which is an embodiment that is encompassed by the "at least one of" language set forth in (ii). The specification fails to conceive of T cell immunogenic epitopes. Generic language of the specification drawn to immunogenic epitopes does not support the now claimed subgenus of T cell epitopes comprising at least 6 amino acids. Further, one skilled in the art would not have been convinced that Applicants were in possession of the genus of T cell epitopes because the epitopes recognized by T cells are peptide fragments which have been presented by an

accessory cell and presented in the cleft of a class I MHC antigen or class II MHC antigen molecule, thus the T cell recognizes the peptide bound to syngeneic MHC. Since a continuous primary sequence is necessary for T cell recognition but not for antibody recognition, the epitopes recognized by each are different (Herbert et al, The Dictionary of Immunology, Academic Press, Fourth Edition, 1995, pages 58-59). The use of antibodies to clone SEQ ID NO:2 does not describe T cell epitopes since they are different from B cell epitopes. Further, the specification as filed does not describe fragments of SEQ ID NO:2 capable of being presented in syngeneic MHC and recognized by T cells and as such, one skilled in the art would not recognize that Applicants were in possession of a T cell epitope as defined by the art. Peptides that bind in the MHC class I or Class II grove are not considered T cell epitopes as defined in the art. Applicants argue that one could search for such by using methods in the art. This is not persuasive, the standard for written description is not make and test to discover, but possession as conveyed by the written description of the specification as filed. Applicants' passage at page 17, lines 30-18 are merely prophetic. This passage is broader than T cell epitopes. Prophetic immunogenic epitopes do not provide for written description of the subgenus of T cell epitopes. Applicants admit in the response filed March 26, 2004 that they have not found any T cell epitopes (paragraph bridging pages 25-26). As such, the specification does not convey with reasonable clarity to those of skill in the art that Applicants were in possession of the claimed invention at the time of filing.

New Objections/Rejections

Claims 27-33 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claims recite :"the protein or peptide of claim 5" , however this improperly broadens embodiment (i) of claim

5, because claim 5 is the full-length protein, whereas claims 27-33 apparently claim fragments thereof. As such, these claims do not properly further limit claim 5 embodiment (i). Correction is required.

Claims 5, 7, 10, 22-25 and 27-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 5, 7, 10, 22-25, and 27-33, the claims recite "protein or peptide" or "peptide or protein". Neither the claims nor the specification defines any difference in the metes and bounds of these two terms. As such, the skilled artisan would not be readily apprised of the difference in scope between these two terms and would not be aware of what subject matter is infringing on one but not the other. Applicant's claims should clearly define a difference in scope between these two terms. If no difference in scope is sought for patent protection, Applicants are directed to delete one of the terms inasmuch as the use of two alternatively presented terms having the same scope provides for confusion as to what is exactly being claimed. If Applicants intend the two terms to have a different scope, then Applicants should point to the specification by page and line number where written description support can be found.

As to claim 5 embodiment (ii), the claim recites "which consists of an amino acid sequence which is a subsequence, at least 6 amino acids in length, of at least one of said isolated protein of (i) above.." and it is not clear from the punctuation that the subsequence must be at least 6 amino acid in length. It is unclear if "at least 6 amino acids in length" relates to the original protein or peptide, the subsequence or the second recitation of protein or peptide in (ii).

As to claims 7 and 10, these claims are drawn to a composition but only provide for a single component. A composition is conventionally defined as having two or more

elements (i.e. compound) as such, they appear identical in scope to the claimed polypeptide. Applicants should define the difference in scope between claims 5, 7, and 10.

Double Patenting

Applicant is advised that should claim 5 be found allowable, claims 7 and 10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). There is no readily discernable difference between the protein and compositions comprising only the protein per se. This issue may be obviated by adding a second component to the kit or composition to provide for a difference in scope between the claims.

Claim 5, 7, 10 and 27-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Melgosa et al. (FEMS Microbiology Letters Vol. 112, No. 2, pp. 199-204, September 1993).

Applicants' arguments and evidence is not persuasive in view of the current claim structure. The claim only requires that the isolated protein of (i) be free of any other chlamydial protein. It does not require the peptide of (i) to be free of any other chlamydial protein. Further, the limitation does not apparently apply to the "peptide or protein" of (ii). As such, Applicants own claim construction does not obviate this rejection even in light of the additional declaration by Dr. Burkelund.

The following claim construction would obviate this issue.

Claim A. An isolated *Chlamydia penumoniae* protein free of any other chlamydial protein, wherein said isolated protein comprises the amino acid sequence as set forth in SEQ ID NO:2.

Status of Claims

Claims 5, 7, 10, 22-25 and 27-33 stand rejected. Claims 1-4, 6, 8, 11, 13 and 15-18 and Species SEQ ID NO:4, 6, 8, 10, 12, 14, 16, 18, 20, 22, and 24 are withdrawn from consideration.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Pat A. Duffy

Patricia A. Duffy

Primary Examiner

Art Unit 1645